

# REFRACTIVE KERATOPLASTY: KERATOPHAKIA AND KERATOMILEUSIS\*

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RENEWED INTEREST IN FULL TIME OPTICAL CORRECTION of aphakia by means of alloplastic lens substitutes has resulted in a sharp increase in the use of these devices for correction of unilateral and bilateral aphakia. Nevertheless, many ophthalmologists remain concerned regarding the introduction of this additional intraocular step to the cataract procedure. In addition, the long-term presence of an intraocular foreign body may result in an unacceptable increase in immediate and delayed postoperative complications, as in two previous experiences with the large-scale use of alloplastic lens substitutes.

For many years, the senior author has been interested in not only the correction of aphakia by intraocular lenses but also the manipulation of the corneal optics for control of residual astigmatic and axial errors. In 1962, his thesis<sup>1</sup> for this Society concerned the use of intraocular lenses. Subsequent papers presented here and elsewhere have detailed his work in the surgical manipulation of the cornea for the control of astigmatism and axial errors induced by cataract and corneal surgery.<sup>2-10</sup>

Doctor Jose Barraquer of Bogota, Colombia, has had parallel interests over as long a period, with particular emphasis on the manipulation of corneal curvatures for the correction of myopia and hyperopia.<sup>11,12</sup> As a result of this interest, he has developed the operations of myopic and hypermetropic keratomileusis and keratophakia, the last of which is the subject of this paper. For the past 15 years, the senior author has been in frequent contact with Doctor Barraquer, observing closely the development of these

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techniques toward the time when they might be applied more generally in a safe and reproducible manner. Some three years ago, we acquired the first production model of the Barraquer cryolathe as well as his microkeratome set. Our clinical trials were delayed almost two years to allow some additional technical and computational refinements to be made by Doctor Barraquer. In July 1977, the two authors attended the first practical course in refractive surgery at the Barraquer Institute in Bogota. After three months of laboratory practice, we performed the first keratophakia done in the United States on October 11, 1977.<sup>10</sup> This paper will present the results of our first 16 operations, the last of which was performed only one week ago.

The value of any new surgical technique, no matter how effective it may be in the hands of its developer, depends ultimately on the reproducibility of the technique, that is, its results when performed by several surgeons working independently and following explicitly the directions of the developer. Ainslie in England has already reported the duplication of Barraquer's results using the latter's earlier technical specifications and prototype instrumentation.<sup>13</sup> In the interim, however, Barraquer has introduced significant improvements in the technique, particularly with regard to the refinement of the mathematics, as well as some simplification of the instrumentation and surgical technique. The mathematical refinements have been made possible by the new, small, powerful, programmable calculators. We are now using the Texas Instrument TI-59 calculator, which allows the consideration of many more variables (some 400 more program steps than was possible with earlier models used). This has made possible more refined programs which can compute quickly and accurately during surgery the cutting parameters for the tissue lens. This has significantly reduced the error and increased the accuracy and reproducibility of our results allowing us to duplicate very closely the most recent results of Barraquer and his associates.<sup>14</sup>

Because of the excellent technical instruction and detailed technical advice provided by Doctor Barraquer, we have been able not only to perform the operation but also to understand the principles involved so as to be able to make necessary refinements and adjustments intraoperatively.

#### SURGICAL PRINCIPLE AND TECHNIQUE

We have performed the operation of keratophakia combined with

intracapsular cataract extraction in all but one patient in which the technique of hypermetropic keratomileusis was used. Keratophakia was chosen, following the advice of Barraquer, since it offers initially greater safety than keratomileusis. When the surgeon is thoroughly familiar with the keratophakia technique, he can more readily correct intraoperative technical errors which can result from a poorly or inaccurately performed hypermetropic keratomileusis technique.

The object of either technique is to increase the anterior corneal curvature without changing the corneal diameter. In keratophakia, a homograft disc is inserted between the corneal lamellae which have been accurately separated with a microkeratome. This disc has been ground while in the frozen state to a power calculated to correct the aphakic ametropia. The disc induces an increase in curvature of the anterior corneal lamella to achieve the desired correction.

In the case of keratomileusis, the correction is ground directly into the microkeratome resected anterior lamellar cap. No interlamellar disc is used. The tissue lens of calculated power is ground in a 6-mm central optical zone, concentric with the thinned periphery. This optically ground cap is sutured in place. When it is healed, the sulcus which has developed in the thinned corneal periphery induces a relative steepening in the corneal curvature. Because no interlamellar disc is inserted the thickness of the cornea is not increased as in keratophakia, and there is only one interface. Thus more rapid healing takes place and earlier restoration of acuity is obtained.

It is evident that neither of these techniques involves intraocular surgery, though it cannot be said that they are truly noninvasive. There is, therefore, little opportunity for either operation to complicate, or to be complicated by, the cataract procedure. A normal intracapsular cataract extraction can be performed prior to, at the same operation, or subsequent to either refractive keratoplasty procedure. The outcome of the corneal procedure is not affected by any complication of the intraocular surgery.

In performing this operation, the authors have acted as a team. One surgeon performs the surgery on the ocular globe — that is, the microkeratome resection of the anterior lamellar corneal cap, its resuturing, or in the case of keratophakia, with the inclusion of the interlamellar disc — and the cataract procedure which, in all instances, has been done by the intracapsular method.

The second member of the team takes the necessary preoperative and intraoperative patient and donor measurements and enters the data into the TI-59 programmable calculator from which the final cutting parameters are calculated. These cutting parameters are set on the lathe micrometers. The homograft disc frozen by carbon dioxide is then cut to the computer-determined dimensions.

Preoperative measurements which are used in the program include the A-scan determined length of the globe, corneal curvatures, and desired dioptric correction. Intraoperatively the thickness of the microkeratome resected donor corneal cap is determined first in the unfrozen and then in the frozen state, as well as the thickness of the donor posterior corneal lamella. In our earlier operations, we determined also the thickness of the microkeratome resected anterior corneal lamellar cap of the patient's cornea. However, because of several problems that we experienced with cutting the donor disc, as an added safety factor we have elected to omit this measurement in favor of preparing the interlamellar disc prior to the microkeratome resection of the patient's anterior corneal lamellar cap.

When resuturing the patient's corneal lamellar cap, it is important to use an obliquely placed antitorque continuous suture so that the tension of the crossover suture loops does not rotate the cap in its bed.<sup>15</sup>

#### PATIENT SELECTION

The patients selected had essentially monocular cataract and averaged 66.7 years of age (range 49-84) (Table 1). Four of 16 patients had known maculopathy before surgery. Preoperatively, the keratometry averaged 42.95 D.

#### RESULTS AND COURSE

The postoperative management of these patients does not differ substantially from that of the usual cataract patient. Decadron drops are used 3 times daily and chloramphenicol drops, twice daily, in the operated eye. Additionally, 5% sodium chloride drops are used 3 times a day to aid in the dehydration of the anterior corneal

TABLE I.  
COMPARISON OF PRE- AND  
POSTOPERATIVE ACUITIES (WITH  
AND WITHOUT CORRECTION)  
KERATOPHAKIA CASES.

	VISUAL ACUITY		
	PREOP CC	POSTOP SC CC	
20/20-40	0	1 7	
20/40-80	1	6 5	(2 SMD)
20/80-200	2	5 0	
20/200	13	3 2	(2 SMD)
	16		

lamellar cap and interlamellar disc. The continuous antitorque suture is removed between the sixth and eighth week. Earlier removal invites elevation of the graft edge which can result in complications involving the epithelium.

Early postoperatively, the return of visual acuity has been prolonged and variable. Recently, where we have used a revised computer program which yields a thinner interlamellar disc this has improved considerably. Earlier, we purposely selected patients with macular disease. Encouraged by our results, however, we have performed these techniques on a number of eyes with normal macular function. In most instances, these eyes have corrected vision approaching the 20/30 to 20/20 level (Table I). The variable rate of visual acuity recovery may be related to the freshness of the donor material, its state of hydration, and the thickness of the donor disc. Also, our suture pattern compensates not only for torquing but also for anticipated cylindrical error induced by the surgical procedures. This is reflected as a significant cylindrical error until all sutures are removed. Surgical keratometry using the senior author's instrument is essential to monitor the accurate tensioning of suture loops to assure even distribution across the healing corneal wounds.<sup>4,9,16</sup>

It has been observed that there is also a significant early hyperopic error which reduces gradually during the first few postoperative months. Postoperatively, the average keratometry measured 52.77D thus giving an average net increase in corneal dioptric power of 9.82D. Residual refractive error in those eyes where all sutures have been removed gave a spherical equivalent of +2.13D with an average cylindrical error of 1.54D.

Complications have been primarily technical. Patients 1 and 3 (Table II) experienced wound dehiscence following too-early su-

TABLE II  
PERTINENT AGE, SEX, ACUITY, REFRACTION DATA ON SIXTEEN  
KERATOPHAKIA PATIENTS (ALL OPERATIONS COMBINED WITH INTRACAPSULAR  
CATARACT EXTRACTION). COMPLICATIONS NOTED UNDER REMARKS

PT. NO.	AGE/SEX	ACUITY*		WEEKS		REFRACTION	REMARKS
		PREOP	POSTOP	FOLLOW-UP			
1	55 M	20/40	20/25	22	+ .25 + 1.00×180		Dense PSC cat; resutured wound
2	53 F	FC	20/30	20	+1.00 + 5.00×90**		
3	71 F	FC	20/60	19	+2.00 + 1.00×135		Repeat keratophakia for dehiscence
4	71 F	FC	20/30	18	pl + 2.00×40		
5	80 F	FC	20/30	18	+ .75 + 2.50×180		
6	77 F	20/200	20/50	15	+2.00 + 1.00×80		SMD
7	49 M	20/70	20/25	13	+3.00 + 3.50×150**		Irregular resection
8	66 F	20/200	20/60	10	+1.00 + 2.25×10		SMD
9	57 M	HM	20/60	9	-2.50 + 1.00×40		
10	71 M	FC	20/50	9	-2.25 + 4.50×165**		SMD (no recent follow-up)
11	84 M	HM	20/400	8	—		SMD (no recent follow-up)
12	71 F	HM	20/800	9	—		
13	56 F	20/200	20/30	4	+5.50 + 4.50×50**		
14	60 F	20/200	20/25	4	+3.50 + 2.25×110**		
15	67 M	20/100	—	—	—		
16	79 M	20/400	—	—	—		

\*Best corrected

\*\*Sutures still in place

ture removal. Patient 1 required resuturing without complication. Patient 3 developed epithelial ingrowth after resuturing was delayed and a repeat keratophakia was performed. Patient 7 had an irregular resection with the microkeratome and complained of monocular diplopia early in the postoperative course. In our initial eyes, we also found multiple foreign bodies which have been almost completely eliminated in later operations by using filtered solutions and carefully examining for and removing foreign bodies from the disc before suturing. Following our earlier operations, we encountered a higher incidence of dehiscence of the hyaloid membrane as compared to intracapsular cataract extraction without keratophakia but the small number of cases are not yet statistically significant.

#### SUMMARY

We have presented our early experience with the refractive keratoplasty techniques of Doctor Jose Barraquer — keratophakia and hypermetropic keratomileusis. In contradistinction to the alloplastic lens substitutes currently being employed for the integral correction of aphakia, his techniques would seem to offer a more permanent, more physiologic, full-time optical correction of the aphakic state. Their use is limited only by the condition of the patient's cornea and, in fact, may be applied not only in aphakia but also in phakic eyes with higher degrees of hyperopia or myopia. In the opinion of the authors, the refractive keratoplasty techniques of Barraquer can be performed by any well-instructed ophthalmic surgeon. These techniques offer to many patients a satisfactory and potentially a physiologically superior alternative to alloplastic lens substitute for aphakic correction.

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## DISCUSSION

DR ARTHUR GERARD DEVOE. Doctor Barraquer has performed this operative procedure on a large number of patients. I have been to Bogota, observed the procedure, and seen a number of postoperative patients. There is no question that this procedure is a perfectly feasible physiological operation, but it does take a considerable amount of surgical skill, practice, and ingenuity. The instrumentation is complex and of course expensive. We can do nothing but congratulate those individuals who have had the courage, skills, and ability to work on these new techniques which are highly sophisticated, complicated, and beautiful to watch. I cannot help but feel, however, that in view of the many simpler methods of overcoming refractive errors, that keratophakia and keratomileusis must in many cases be considered something of an overkill.

Thank you for the privilege of discussing this paper.

DR DAVIS G. DURHAM. I want to report on one case that I sent to Doctor Barraquer in Bogota, Columbia. This was a keratomileusis for myopia in a

20-year-old girl who could not wear contact lenses. She needed approximately  $-10.00$  sphere. The two observations I wish to make were that in returning to the United States the first eye had a  $+0.25$  sphere refraction. Within a year this gradually returned to a slight myopia. A year later she had the other eye done and this returned to about a  $-1.00$  sphere. The other point was the minimal scarring. Grossly there was no scar visible on the cornea. With the slit lamp one could barely see a little haze in the periphery of the cornea. I was most impressed with this procedure.

DR EDWARD A. DUNLAP. As an ex-squint man I stand here in awe and trepidation. I, too, would like to compliment the authors and particularly Doctor Barraquer for the brilliance of the concept and the technique and for the intestinal fortitude in effecting it. In my practice I had cases of anisometropia, some with amblyopia, some with squint. Some of the patients with squints had amblyopia and some didn't. Although this paper deals primarily with cataracts, keratomileusis was considered. I would like to ask if it is feasible or even possible to manage anisometropia both as a treatment and a prophylactic measure with keratomileusis. Then if you want to leave the realm of sophistication and get to a total esoteric matter, could the management of accommodative esotropia be effected by keratomileusis?

DR MICHEL MATHIEU. In cases where you correct aphakia and obtain a steep modification of the corneal curvature between the centre and the periphery, can this affect the normal spreading of the tear film and create dry spots or similar disturbances?

DR JOSE I. BARRAQUER. Mr. President, Mr. Secretary, Ladies and Gentlemen: I wish to thank you for the privilege of letting me attend the annual meeting of the American Ophthalmological Society, during which one of the first papers on refractive surgery written by someone other than myself has been presented.

Refractive surgery is a new branch of corneal surgery. As a result of the refinement of its techniques and instruments, it may be performed by corneal microsurgeons with very uniform results. However, to perform this surgery one has to be extremely precise, since the measure unit used is not the millimeter, but the hundredth of a millimeter. This unit, translated to optical terms, is the equivalent of one diopter. This high precision, as can be easily understood, can be obtained only with the aid of mechanical means. None of us would try to cut manually a common optical lens, not to mention a contact lens, as done in the times of Van Leeuwenhoek (1632-1723).

Up to now, the main indication for refractive surgery was bad tolerance to conventional or contact lenses, but at present, due to the satisfactory results obtained, we are performing it combined with cataract surgery, to

reduce aphakic ametropia. The refractive procedure can also be performed as secondary surgery, since it is a totally extraocular operation. I am convinced that refractive surgery will be the surgery of choice in the near future, not only because of the refinement of its techniques, but also as a result of the growing demand of patients who demand surgical correction, or at least a decrease in their ametropia.

I want to congratulate Doctor Troutman and Doctor Swinger for their paper and express to them my fervent wishes for a great success in the near future.

Thank you.

DR RICHARD C. TROUTMAN. I would like to thank Doctor DeVoe and in particular Doctor Barraquer for their discussions as well as the other discussors for bringing up several important points. Doctor DeVoe raised the question of cost of the instrumentation which is considerable. However, considering the cost of CT scanners and many other high-priced instruments, it is rather cheap. In fact, if one could turn in one's old unused phacoemulsifier one could buy the equipment with ease.

Complications I think are quite minimal when related to those encountered with alloplastic lens substitutes. I would like to have this latter term accepted rather than the term "intraocular lenses." With alloplastic lens substitutes, the complications increase with the time the implants remain within the eye. This is the experience at the present time paralleling our experience with two past episodes of mass implantation.

Considering better contact lens technology and though there have been many advances, nevertheless we still have a number of patients who cannot wear contact lenses. Although this number may be small they represent a very real segment of our population. The question of doing keratophakia as a secondary procedure rather than primarily with the cataract surgery is a good one and we intend to do this. So far, however, we have had patients who have successfully worn a contact lens in one eye or had an intraocular lens in one eye who were concerned about wearing a contact lens in the second eye because they felt they might not be able to find their primary contact lens. In particular, there is the patient who is unilaterally pseudophakic of which there are thousands in the United States at the moment. Keratophakia is particularly suitable in this group since the patient has already evidenced that he cannot wear a contact lens. According to the criteria of Jaffe, he should not have an intraocular lens in the second eye, therefore he has no alternative but to remain unilaterally pseudophakic unless a keratophakia is done when the second cataract is removed. When patients request intraocular lenses we advise keratophakia as an alternative.

The question raised by Doctor Durham speaks for itself. Doctor Dunlap raised the question of anisometropia which Doctor Barraquer has answered. He did not comment on accommodative esotropia, but he has

operated upon some patients with this condition. Of course, this would have to be a mature patient with a stabilized hyperopic refraction. As Doctor Barraquer told us, it is very nice if the young lady looks at her fiance or her friend with straight eyes.

I would like to thank the Society for the opportunity to present this paper and Doctor Barraquer in particular for having come to join this audience in the discussion.

Thank you.